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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,704	04/23/2001	Shoukat Dedhar	KINE001CON2	5167

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BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,704	DEDHAR ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10 and 13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-10, and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

This Office Action is a response to the Amendment after Final, filed December 9, 2003.

Claims 2, 3, 11, and 12 are canceled. Claims 1, 4, 6-8, 10, 13 and 15-17 have been amended.

Claims 1, 4-10, and 13-18 are pending in the instant application.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5-10 and 13-18 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is withdrawn in view of Applicant Amendment to the claims to recite, "A method of inhibiting inflammation in an *in vitro* model, the method comprising contacting said *in vitro* model with an effective dose of a compound that inhibits integrin likened kinase (ILD) as set forth in SEQ ID NO:1".

Claims 1, 4, 5-10 and 13-18 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting inflammation in a host *in vitro*,

comprising contacting said host with an effective dose of a compound that inhibits integrin linked kinase (ILK) as set forth in SEQ ID NO:1, does not reasonably provide enablement for a method of inhibiting/preventing inflammation in a host *in vivo*, comprising contacting said host with an effective dose of a compound that inhibits integrin linked kinase (ILK) as set forth in SEQ ID NO:1. This rejection is withdrawn in view of Applicant Amendment to the claims to recite, "A method of inhibiting inflammation in an *in vitro* model, the method comprising contacting said *in vitro* model with an effective dose of a compound that inhibits integrin likened kinase (ILD) as set forth in SEQ ID NO:1".

After careful reconsideration of the claims, a new grounds of rejection is set forth as presented below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-10, and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Heraud et al. (Journal of Biological Chemistry, 1998 Vol. 273:17917-17823).

Claims 1 and 10 are drawn to a method of inhibiting/preventing inflammation in an *in vitro* model, comprising contacting said *in vitro* model with an effective dose of a compound that inhibits integrin linked kinase (ILK) as set forth in SEQ ID NO:1. Claims 4-9 and 13-18 are dependent on claims 1 and 10, respectively, and include all the limitation of claims 1 and 10,

respectively, with the further limitations, wherein said compound comprises a small organic molecule; wherein said compound blocks ILK catalytic activity; wherein said compound decreases the available level of PtdIns (3,4,5) P_3 in a cell; wherein said compound is wortmannin, wherein said compound is LY294002; and wherein cellular migration is inhibited.

It is noted that claims 1, 4-10, and 13-18 disclose one step, contacting an *in vitro* model with a compound that inhibits integrin-linked kinase (ILK).

Heraud et al. disclose contacting platelets with increasing doses of wortmannin or LY294002 *in vitro*. Heraud et al. disclose pretreatment of platelets with wortmannin or LY294002 inhibited platelet spreading on fibrinogen matrix (see Fig 3, for example) and platelet adhesion (see Table I, for example). Although Heraud et al. do not disclose the effect of wortmannin or LY294002 on the available level of PtdIns (3,4,5) P_3 or cellular migration of pretreated platelets, Heraud et al. disclose the one step recited by the claims, and therefore the platelets pretreated with wortmannin or LY294002 of Heraud et al. are considered to decrease the available level of PtdIns (3,4,5) P_3 in a cell and inhibit cellular migration, as recited in the instant claims, absent evidence to the contrary.

It is noted that there is no evidence of record to suggest that the platelets pretreated with wortmannin or LY294002 disclosed by Heraud et al. will not decrease the available level of PtdIns (3,4,5) P_3 or inhibit cellular migration as recited in the instant claims.

Therefore Heraud et al. anticipate the instant invention.

Claims 1, 4-7, 9, 10, 13, 14, 15, 16 and 18 are rejected under 35 U.S.C. 35 U.S.C. 102(b) as being anticipated by Norman et al. (Journal of Medicinal Chemistry, 1996 Vol. 39:1106-1111).

Claims 1, 4-7, 9, 10, 13, 14, 15, 16 and 18 are drawn to the invention as described in the 35 U.S.C. 102(b) rejection against claims 1, 4-10, and 13-18 above.

Norman.et al. disclose the *in vitro* effects of wortmannin and wortmannin analogs in C3H mammary cell line. Normal et al. disclose the effect of wortmannin on PI 3-kinase activity and cellular toxicity in C3H cells (see Table 3, for example). Although Norman et al. do not disclose the effect of wortmannin on the available level of PtdIns (3,4,5) P_3 or cellular migration of C3H cells, Norman et al. disclose the one step recited by the claims, and therefore the C3H cells treated with wortmannin of Norman et al. are considered to decrease the available level of PtdIns (3,4,5) P_3 in C3H cells and inhibit cellular migration, as recited in the instant claims, absent evidence to the contrary.

It is noted that there is no evidence of record to suggest that C3H cells treated with wortmannin disclosed by Norman et al. will not decrease the available level of PtdIns (3,4,5) P_3 or inhibit cellular migration as recited in the instant claims.

Therefore Norman et al. anticipate the instant invention.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0564.

tcg
January 20, 2003

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER